UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,545	03/28/2001	John kung	JBP0547	3384

27777 7590 06/03/2004

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/819,545	KUNG ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-60* is/are pending in the application.

4a) Of the above claim(s) *47 and 48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/5/2003; 12/17/2004,
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2004 has been entered.

Claims 47-60 are currently pending. Claims 49-60 are under consideration as they are directed to the elected invention set forth in Paper No. 3. Claims 47-48 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Any rejection that is not addressed in this Office Action is considered obviated in view of the amendments.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 49-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending Application No. 10/020623, 10/414751. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope and are directed to compositions comprising retinol, ascorbid acid glycoside and acrylate copolymer. In fact each sets of claims anticipate the other set of claims. Therefore, once in possession of each set of claims, one of ordinary skill in the art would have practiced the other set of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 49-60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Froix et al US Patent 5,851,538, in view of Simon et al US Patent 5,730,972.

The instant claims are directed to compositions comprising an amount of a composition consisting essentially of ascorbic acid-2-glucoside, Acrylates/C0-30 Acrylate cross polymers and retinol. Examiner views the instant claims to contain any type of compound so long as ascorbic acid-2-glucoside, Acrylates/C0-30 Acrylate cross polymers and retinol exists in the final composition. There is no requirement in the instant claims that the penetration-enhancing composition keeps its integrity in the final topical composition that is instantly claimed. In another word, the penetration enhancing composition can be a solution containing ascorbic acid-2-glucoside, acrylate copolymers and retinol, which can be combined with other conventional compounds to form the instantly claimed topical composition. Therefore, the transitional phrase "consisting essentially" in line of the indepenendt claim 49 does not narrow the scope of the claims.

Froix et al teach topical skin formulations of Retinoid suspended in esters of acrylic or methacrylic polymers (see col 4 lines 14-25, claims 1, 5-10) in combination with antioxidants such as ascorbic acid (vitamin C) to lower the irritancy caused by retinoids when applied on skin (see example II, and claim 1-10). Froix et al however do not specifically use a sugar ester of ascorbic acid in their composition.

Simon et al disclose compositions for combating skin marks comprising at least one sugar such as ascorbyl-2-glucoside, and a UVA screening agent (see abstract, claim 1 and 5). The composition of Simon et al also comprise a polymeric emulsifier

such as Pemulen, a polyethylene alcohol such as polyethylene glycol stearate, and a moisturizing agent such as glycerol (see col 7-9; examples 2-4). Simon specifically states that ascorbic acid glucoside is highly water soluble and is converted to Vitamin C when administered to skin (see col 2, lines 51-60).

Both Froix and Simon teach methods of enhancing topical delivery of active agents, therefore, their teachings are viewed as being in the same field of endeavor.

Although Froix does not use an ascorbic acid glycoside in his compositions, it would have obvious to one of ordinary skill in the art at the time of invention to modify Froix's composition by using an ascorbic acid precursor of Simon et al in place of his vitamin C, because as stated by Simon, the ordinary skill in the art would have expected the ascorbic acid glycoside to convert to vitamin C.

Further, Froix teaches that the combination of Vitamin C and retinoid together in a composition improves the skin irritation caused by retinoids, thus, the ordinary skill in the art would have had a reasonable expectation to reduce skin irritation of retinoids when administering it with any Vitamin C derivative. Thus, substituting Vitamin C with its art equivalent, ascorbic acid glycoside, would have been obvious.

Finally, absence of using unexpected results, optimizing the concentrations of individual ingredients is well within the scope of a skilled artisan, therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to modify Froix composition to contain ascorbic acid glycoside, as taught by Simon, and further optimize the concentrations by routine experimentation for their respective pharmacological effects.

4. Claims 49-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al US Patent 6,544,531 in view of Simon et al US Patent 5,730,972.

Cole teaches retinol compositions comprising retinol, acrylate C10-30 Alkyl Acrylate, and a ascorbyl glucoside (see abstract, Examples 5-6, claims 1-2, 4). Cole does not teach the use of ascorbic acid glycoside.

Simon provides for the use of ascorbic acid glycoside.

As it is well known in the art that ascorbic acid derivatives can improve the irritability of retinol, it would have been obvious to one of ordinary skill in the art at the time of invention to use ascorbic acid –2-glycoside of Simon in place of the ascorbic acid sources of Cole, because the ordinary skill in the art would have expected the same functional properties from ascorbic acid-2-glycoside of Simon. Furthermore, absence of showing the criticality, optimizing the concentrations of the ingredients in such compositions would have bee attainable by routine experimentation.

5. Claims 49-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farng et al US Patent 5,643,584 in view of Simon et al US Patent 5,730,972 and Patel US patent 4,863,970.

Farng teaches methods of improving retinoid penetration comprising compositions comprising a retinoid (recited in Farng as a tretinoin), a polyoxyethylene alcohol surfactant such as polyethylene glycol glyceryl stearate, an antioxidant such as ascorbic acid, and an acrylic polymer such as a carbopol. (see col 2, lines 5-35; col 5, lines 1-20; examples 1-5; claim 19). Frang explicitly encourages the use of surfactants in amounts effective to enhance penetration of retinoid into skin. (see col 2, lines 7-10).

The concentrations of each such components of Farng fall within the ranges of the instantly claimed components. Farng only fails to use ascorbic acid-2-glucoside.

Simon teaches that saccharides derivatives of ascorbic acid such as ascorbic acid glucosides are highly water-soluble and are converted to Vitamin C when administered to skin to provide the same function as the ascorbic acid. (see col 2, lines 51-60). Therefore, ascorbic acid glucoside is considered to be a functional art recognized equivalent to Ascorbic Acid for at least topical administrations. Further, Simon teaches topical formulations of ascorbic acid glucosde with an acrylate polymer such as pemulen and polyethylene glycols such as polyethylene glycol stearate. (see col 7-9, examples 3-4).

Patel is only provided to set forth that polyoxyethylene alcohols are well-recognized surfactants with penetration enhancing properties and are readily used in the art to improve skin permeation of drugs in topical formulations. Accordingly many polyoxyethylene alcohols are enumerated in this patent including oleyl alchol, glycerol monoleate etc... (see abstract; col 4, lines 56-67; col 6, lines 1-60).

Accordingly, since ascorbic acid of Farng and ascorbic acid glucoside of Simon are viewed to be functional art equivalents, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute ascorbic acid of Farng with the ascorbic acid glucoside of Simon, because substituting art recognized equivalents for purposes of providing a same function is *prima facia obvious.* The ordinary skill in the art would have had a reasonable expectation of success in observing the same functions employing ascorbic acid glucoside of Simon as Ascorbic acid of Farng.

Further, absence of showing unexpected results employing any art equivalent polyoxyethylene surfactant as enumerated in Patel and encouraged by Farng would have been well within purview of one of ordinary skill in the art.

Conclusion

6. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ss

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200